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10/074,250	02/14/2002	Laura E. Niklason	1579-637	5073

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EXAMINER	
CHONG, YONG SOO	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/074,250
Filing Date: February 14, 2002
Appellant(s): NIKLASON ET AL.

Mary J Wilson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/11/2006 appealing from the Office action mailed 4/10/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is incorrect. Upon further consideration, Examiner has decided to withdraw both 35 USC 112 rejections on claim 1 over written description and enablement. The lone remaining rejection to be reviewed on appeal is whether claims 1, 10-11 lack novelty under 35 USC 102(b) over Black (US Patent 5,527,778).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Black (US Patent 5,527,778)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10-11 are rejected under 38 U.S.C. 102(b) as being anticipated by Black (US Patent 5,527,778).

Black discloses that well-known neuropharmaceutical agents such as chemotherapeutic agents, in particular, methotrexate (see col.4 line 57 to col.5 line 10) to be administered to a patient are useful in methods of treating abnormal brain tissue including subarachnoid hemorrhage, head injury (head trauma) and cerebral ischemia, and opening abnormal brain tissue capillaries in a patient, i.e., a mammal (see abstract, col.4 lines 1-9).

Thus, the disclosure of Black anticipates claims 1 and 10-11.

(10) Response to Argument

Appellant argue that Black relates to "a method for selectively opening abnormal brain tissue capillaries (roughly 10 microns in diameter) ... to allow selective passage of ... neuropharmaceutical agents in to abnormal tissue," whereas the claimed invention relates to the treatment or inhibition of cerebral vasospasm, which is a disease of small- to medium-sized arteries, several mm in diameter. Appellants argue that they have realized that vasospasms following subarachnoid hemorrhage (SAH) are caused by thickening of the wall of the artery and by blocking the growth and proliferation that occurs in the arterial wall, this syndrome is treated. Thus, the claimed method, in contrast to Black, has nothing to do with capillaries, or with inducing permeability within capillaries, or with delivering drugs to injured brain tissue.

Appellant also argue that Black in no way teaches that any or all of these neuropharmaceutical agents could be used to treat any or all of the abnormal brain tissues. Furthermore, absolutely nothing in Black teaches administration of a chemotherapeutic agent to treat SAH.

This is not persuasive because at the outset the fact remains that Black clearly teaches a method of treating abnormal brain tissue, such as SAH, by administering well-known neuropharmaceutical agents, such as methotrexate. Appellant attempts to differentiate the patient population by arguing that the claimed invention is related to arteries and not capillaries. Again, Black clearly discloses treatment of patients suffering from SAH, therefore it is inherent that some or all of the patients suffering from SAH will also suffer from cerebral vasospasms. Accordingly, the etiology and/or

mechanism of action of the disease are given little patentable weight. Appellant has admitted to as much in the recitation on page 16 of the Appeal Brief that "examples of specific types of abnormal brain tissue are indicated to include, in addition to SAH, gliomas, metastatic brain tumors, head injury, meningitis, brain abscess, and multiple sclerosis." Furthermore, what Appellant asserts herein is deemed to be merely the proposed or claimed mechanism of action of the treatment. Note that the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known, i.e., administering methotrexate to the same patient herein having brain tumors or cancers (see abstract of Black's patent) even though applicant has proposed or claimed the mechanism. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Further, the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above. Moreover, mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Yong S. Chong, Ph.D.
Patent Examiner
Art Unit 1617

ysc
February 27, 2007

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